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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,705	06/23/2003	Mark Yang	2498-111	5744

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	

ART UNIT	PAPER NUMBER
1753	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,705	YANG ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/20/2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *IDS of 10/27/2003*.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (US 5,366,609) ("White") in view of Patko et al. (US 6,153,085) ("Patko") and Ou-Yang et al. (US 2003/0204313 A10 ("Ou-Yang')

Addressing claim 1, White discloses a portable multi-functional electrochemical biosensor system, comprising

a sample cell (18) the sample cell having a reaction zone (20) on which a substance is placed to react with a corresponding selected analyte (col. 4:33-36) and having a t least two independent electrodes (24,26) which are not connected to each other (Figure 3), wherein one of the two electrodes is a reference electrode (24), and the other is a working electrode (26), when a detective reaction occurs, the electrodes output an electrochemical reaction signal (col. 5:53-58);

a pluggable information memory (30), corresponding to the sample cell during detection (col. 5:3-18), the pluggable information memory being able to provide parameters used for analyzing the concentration of the corresponding selected analyte (claim 9; col. 5:3-18; and col. 5:66 – col. 6:13); and

a multi-functional signal analysis processor (16, Figure 3) having a microprocessor (59), a read memory (ROM) (30, Figure 3) and an environmental temperature sensor (54), the multi-functional signal analysis processor having at least two input terminals which are connected to the sample cell and the pluggable

information memory, respectively (Figure 1), and when an electrochemical reaction occurs, the microprocessor transferring the parameters from the pluggable information to the read memory so that the concentration of the selected analyte is calculated by using the electrochemical reaction signal output from the sample cell and the parameters provided by the read memory, (col. 4:56 – col. 6:13), and then output (Figures 4-6 and col. 8:36-38);

wherein the biosensor system uses the sample cell and pluggable information memory to detect the concentration of a corresponding selected analyte. See the abstract.

White does not mention (i) providing a plurality of sample cells, (ii) providing a plurality of pluggable information memories, (iii) erasable programmable read/write memory, and (iv) the analyte concentration is calculated with cooperation of the temperature compensation established by the environmental temperature sensor.

As for a providing a plurality of sample cells and a plurality of pluggable information memories, White clearly discloses that the electrochemical biosensor system is not limited to measuring a particular analyte. See col. 3:35-65 and col. 5:27-50. Thus, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide a plurality of sample cells and a plurality of pluggable information memories to allow for a variety of analytes to be measured.

As for providing erasable programmable read/write memory, White uses read only memory (ROM), however, as shown by Patko and Ou-Yang it was known at the time to also use a variety of memories, including erasable programmable read/write

memory, in a portable electrochemical biosensor system. See in Patko the abstract and col. 11:1-41 and paragraph [0007] of Ou-Yang. Barring evidence to the contrary, such as unexpected results, in light of Patko and Ou-Yang the choice of memory, such as erasable programmable read/write memory, will depend on whether data will have to be overwritten and the energy needs of the memory device. See col. 11:1-41 in Patko and paragraphs [0004] and [0019] in Ou-Yang.

As for calculating the analyte concentrations with cooperation of the temperature compensation established by the environmental temperature sensor, although not specifically mentioned by White if not implied is obvious because the temperature sensor output is fed to the microprocessor during measurement (col. 4:65 – col. 5:2) and White discloses enzymatic reactions, which as known in the art are temperature sensitive.

Addressing claim 2, Patko and Ou-Yang both discloses EEPROM memories. See in Patko col. 11:1-23 and paragraph [0019] in Ou-Yang. Again, the choice of memory, from known memories used in electrochemical biosensors, will be based on need to change memory contents and memory energy usage.

Addressing claim 3, for the additional limitations of this claim see in White col. 5:3-18 and col. 5:66 – col. 6:13 and paragraph [0007] in Ou-Yang.

Addressing claim 4, for the additional limitations of this claim see in White col. 8:6-38.

Addressing claim 5, White discloses providing the working electrodes with a reference potential and having a signal amplified via an amplifier and a feed-back resistor, and during the detection, the electrochemical reaction signal output from the working electrode is sent to the multi-functional signal analytical processor for calculating the concentration of the selected analyte. See Figures 3 and 7. White does not mention grounding the reference electrode. However, White discloses that various voltages may be applied to the reference electrode. See col. 5:19-26. Thus, barring evidence to the contrary, such as unexpected results the voltage applied to the reference electrode, which is an intended use, is just a matter of optimizing the voltage for the measurement.

Addressing claim 6, for the additional limitations of this claim see in White Figure 7 and col. 7:50-65.

Addressing claim 7, for the additional limitations of this claim see in White col. 6:35 – col. 7:15 and note the incubation time during which the voltage to the working electrode is removed.

Addressing claim 8, White discloses a portable multi-functional electrochemical biosensor system, comprising

a sample cell (18) the sample cell having a reaction zone (20) on which a substance is placed to react with a corresponding selected analyte (col. 4:33-36) and having a t least two independent electrodes (24,26) which are not connected to each other (Figure 3), wherein one of the two electrodes is a reference electrode (24), and the other is a working electrode (26), when a detective reaction occurs, the electrodes output an electrochemical reaction signal (col. 5:53-58);

a pluggable information memory (30), corresponding to the sample cell during detection (col. 5:3-18), the pluggable information memory being able to provide parameters used for analyzing the concentration of the corresponding selected analyte (claim 9; col. 5:3-18; and col. 5:66 – col. 6:13); and

a multi-functional signal analysis processor (16, Figure 3) having a microprocessor (59), a read memory (ROM) (30, Figure 3) and an environmental temperature sensor (54), the multi-functional signal analysis processor having at least two input terminals which are connected to the sample cell and the pluggable information memory, respectively (Figure 1), and when an electrochemical reaction occurs, the microprocessor transferring the parameters from the pluggable information to the read memory so that the concentration of the selected analyte is calculated by using the electrochemical reaction signal output from the sample cell and the parameters provided by the read memory, (col. 4:56 – col. 6:13), and then output (Figures 4-6 and col. 8:36-38).

White does not mention (i) providing a plurality of sample cells, (ii) providing a plurality of pluggable information memories, (iii) erasable programmable read/write memory, (iv) the analyte concentration is calculated with cooperation of the temperature compensation established by the environmental temperature sensor, and (v) a status detector having two independent electrodes which are connected to a resistor with a const resistance.

As for a providing a plurality of sample cells and a plurality of pluggable information memories, White clearly discloses that the electrochemical biosensor system is not limited to measuring a particular analyte. See col. 3:35-65 and col. 5:27-50. Thus, it would have been obvious to one with ordinary skill in the art at the time of the invention to provide a plurality of sample cells and a plurality of pluggable information memories to allow for a variety of analytes to be measured.

As for providing erasable programmable read/write memory, White uses read only memory (ROM), however, as shown by Patko and Ou-Yang it was known at the time to also use a variety of memories, including erasable programmable read/write memory, in a portable electrochemical biosensor system. See in Patko the abstract and col. 11:1-41 and paragraph [0007] of Ou-Yang. Barring evidence to the contrary, such as unexpected results, in light of Patko and Ou-Yang the choice of memory, such as erasable programmable read/write memory, will depend on whether data will have to be overwritten and the energy needs of the memory device. See col. 11:1-41 in Patko and paragraphs [0004] and [0019] in Ou-Yang.

As for calculating the analyte concentrations with cooperation of the temperature compensation established by the environmental temperature sensor, although not specifically mentioned by White if not implied is obvious because the temperature sensor output is fed to the microprocessor during measurement (col. 4:65 – col. 5:2) and White discloses enzymatic reactions, which as known in the art are temperature sensitive.

As for a status detector having two independent electrodes which are connected to a resistor with a const resistance, Ou-Yang discloses a biosensing meter comprising a status detector, having two independent electrodes which are connected to a resistor with a constant resistance, and to the sample cell of a multifunctional signal analysis processor, and whether the status of the multi-functional signal analysis processor is normal is based on whether the resistance of the resistor detected by the multi-functional signal analysis processor conforms to the built-in resistance of the processor. See Figure 4C and 5 and paragraph [0019]. It would have been obvious to proved a status detector as taught by Ou-Yang (including two independent electrodes in each sample cell) in the invention of White as modified by Patko and Ou-Yang because as taught by Ou-Yang this ensure correct functioning of the biosensor system and thus accurate measurement results. See paragraph [0019].

Claim Objections

5. Claims 1 and 8 are objected to because of the following informality: in line 6 claim 1 and also of claim 8 the examiner suggests replacing "detective" with – detection -- Appropriate correction is required.

Priority

6. Only the first page of the priority document, Taiwan patetn application no. 091113636, has been received.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alex Noguerola
Primary Examiner
AU 1753
August 8, 2005